



4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1335]

Authorization of Emergency Use of Certain Medical Devices During COVID-19; Availability.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance and reissuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to the coronavirus disease 2019 (COVID-19) public health emergency. FDA has issued, and in some cases reissued, the Authorizations listed in this document under the Federal Food, Drug, and Cosmetic Act (FD&C Act). These Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the February 4, 2020, determination by Secretary of Health and Human Services (HHS) that there is a public health emergency that has significant potential to affect national security or the health and security of U.S. citizens living abroad, which involves the virus that causes COVID-19, and the subsequent declarations on February 4, 2020, March 2, 2020, and March 24, 2020, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19, personal respiratory protective devices, and medical devices, including alternative products used as medical devices, respectively, subject to the terms of any authorization issued under the FD&C Act. These Authorizations, which include an explanation of the reasons for issuance and reissuance, are

listed in this document and are available on FDA's website at the links indicated in this document.

**DATES:** These Authorizations are effective on their date of issuance.

**ADDRESSES:** Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the Authorization may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the Authorizations.

**FOR FURTHER INFORMATION CONTACT:** Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces<sup>1</sup>; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. 247d-6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are

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<sup>1</sup> In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the *Federal Register* a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b and 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA<sup>2</sup> concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the

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<sup>2</sup> The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act. Because the statute is self-executing, regulations or guidance are not required for FDA to implement the EUA authority.

## II. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

## III. The Authorizations

Having concluded that the criteria for the issuance and, in some cases reissuance, of the following Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of the following products for diagnosing, treating, or preventing COVID-19 subject to the terms of each Authorization. The Authorizations in their entirety, including any authorized fact sheets and other written materials, are available on the internet from the FDA web page entitled “Emergency Use Authorization,” available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>. The lists that follow include Authorizations issued, in some cases reissued, through April 10, 2020, and we have included explanations of the reasons for their issuance, as

required by section 564(h)(1) of the FD&C Act. FDA is hereby announcing the following Authorizations for in vitro diagnostics:<sup>3</sup>

- CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (CDC), issued February 4, 2020, and reissued March 15, 2020;
- New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel (Wadsworth Center, NYSDOH), issued February 29, 2020, and reissued March 10, 2020;
- Roche Molecular Systems, Inc.'s (RMS) cobas SARS-CoV-2, issued March 12, 2020;
- Thermo Fisher Scientific, Inc.'s TaqPath COVID-19 Combo Kit, issued March 13, 2020;
- Hologic, Inc.'s Panther Fusion SARS-CoV-2, issued March 16, 2020;
- Laboratory Corporation of America's COVID-19 RT-PCR Test, issued March 16, 2020;
- Quidel Corp.'s Lyra SARS-CoV-2 Assay, issued March 17, 2020;
- Quest Diagnostics Infectious Disease, Inc.'s Quest SARS-CoV-2 rRT-PCR, issued March 17, 2020;
- Abbott Molecular's Abbott RealTime SARS-CoV-2 assay, issued March 18, 2020;
- DiaSorin Molecular LLC's Simplexa COVID-19 Direct assay, issued March 19, 2020;
- GenMark Diagnostics, Inc.'s ePlex SARS-CoV-2 Test, issued March 19, 2020;
- Primerdesign Ltd's Primerdesign Ltd COVID-19 genesig Real-Time PCR assay, issued March 20, 2020;
- Cepheid's Xpert Xpress SARS-CoV-2 test, issued March 20, 2020;

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<sup>3</sup> As set forth in the EUAs for these devices, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the devices may be effective in diagnosing COVID-19, and that the known and potential benefits of the devices, when used for diagnosing COVID-19, outweigh the known and potential risks of such devices; and (3) there is no adequate, approved, and available alternative to the emergency use of the devices.

- BioFire Defense, LLC's BioFire COVID-19 Test, issued March 23, 2020;
- Mesa Biotech Inc.'s Accula SARS-Cov-2 Test, issued March 23, 2020;
- PerkinElmer, Inc.'s PerkinElmer New Coronavirus Nucleic Acid Detection Kit, issued March 24, 2020;
- Avellino Lab USA, Inc.'s AvellinoCoV2 test, issued March 25, 2020;
- BGI Genomics Co. Ltd.'s Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV, issued March 26, 2020;
- Abbott Diagnostics Scarborough, Inc.'s ID NOW COVID-19, issued March 27, 2020;
- Luminex Molecular Diagnostics, Inc. Luminex Molecular Diagnostics, Inc.'s NxTAG CoV Extended Panel Assay, issued March 27, 2020;
- NeuMoDx Molecular, Inc.'s NeuMoDx SARS-CoV-2 Assay, issued March 30, 2020;
- QIAGEN GmbH's QIAstat-Dx Respiratory SARS-CoV-2 Panel, issued March 30, 2020;
- Cellex Inc.'s qSARS-CoV-2 IgG/IgM Rapid Test, issued April 1, 2020;
- Ipsum Diagnostics, LLC's COV-19 IDx assay, issued April 1, 2020;
- Becton, Dickinson and Company, BioGX SARS-CoV-2 Reagents for BD MAX System, issued April 2, 2020;
- Luminex Corporation, ARIES SARS-CoV-2 Assay, issued April 3, 2020;
- ScienCell Research Laboratories, ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit, issued April 3, 2020;
- Co-Diagnostics, Inc., Logix Smart Coronavirus Disease 2019 (COVID-19) kit, issued April 3, 2020;

- Gnomegen LLC's, Gnomegen COVID-19 RT-Digital PCR RT-Digital PCR Detection Kit, issued on April 6, 2020;
- InBios International Inc.'s, Smart Detect SARS-CoV-2 rRT-PCR Kit, issued on April 7, 2020;
- Becton, Dickinson and Company's, BD SARS-CoV-2 Reagents for BD MAX System, issued on April 8, 2020;
- DiaCarta, Inc.'s QuantiVirus SARS-CoV-2 Test kit, issued on April 8, 2020;
- Atila BioSystems, Inc.'s, iAMP COVID-19 Detection Kit, issued on April 10, 2020; and
- Certain Molecular-Based Laboratory Developed Tests (LDTs) for COVID-19 that are developed by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high complexity tests and are authorized for use by the singular developing laboratory, issued on March 31, 2020 (a current list of tests included under this EUA is available at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>).

FDA is hereby announcing the following Authorizations for personal respiratory protective devices<sup>4</sup>:

- Certain National Institute for Occupational Safety and Health (NIOSH)-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19

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<sup>4</sup> As set forth in the EUAs, FDA has concluded that: (1) the SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is either reasonable to believe that the authorized respirators may be effective in preventing healthcare personnel (HCP) exposure to pathogenic biological airborne particulates during Filtering Facepiece Respirator (FFR) shortages, and that the known and potential benefits of the authorized respirators, when used to prevent HCP exposure to such particulates during FFR shortages during COVID-19, outweigh the known and potential risks of such products, and (3) there is no adequate, approved, and available alternative for the emergency use.



Public Health Emergency, issued March 2, 2020, with reissuance on March 27, 2020, and March 28, 2020;

- Certain Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, issued March 24, 2020, with reissuance on March 28, 2020 (a current list of respirators included under this EUA is available at <https://www.fda.gov/media/136731/download>); and,
- Certain Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China, issued April 3, 2020 (a current list of respirators included under this EUA is available at <https://www.fda.gov/media/136663/download>).

FDA is hereby announcing the following Authorizations for other medical devices:

- Certain ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as “ventilators”), ventilator tubing connectors, and ventilator accessories, issued March 24, 2020 (a current list of products included under this EUA is available at <https://www.fda.gov/media/136528/download>);<sup>5</sup>
- Battelle Memorial Institute’s Battelle Decontamination System (Battelle CCDS Critical Care Decontamination System), issued March 28, 2020, with reissuance March 29, 2020;<sup>6</sup>

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<sup>5</sup> As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized ventilators, ventilator tubing connectors, and ventilator accessories may be effective in treating patients during the COVID-19 pandemic, and the known and potential benefits of such products, when used to treat patients during the COVID-19 pandemic, outweigh the known and potential risks of such products, and (3) there is no adequate, approved, and available alternative to the emergency use of the authorized ventilators, ventilator tubing connectors, and ventilator accessories for treating patients during the COVID-19 pandemic.

<sup>6</sup> As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Battelle

- STERIS Corporation's STERIS Sterilization Systems (STERIS V-PRO 1 Plus, maX, and maX2 Low Temperature Sterilization Systems), issued April 9, 2020;<sup>7</sup>
- Certain Face Shields, issued April 9, 2020;<sup>8</sup>
- Terumo BCT Inc. and Marker Therapeutics AG's, Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge (an Extracorporeal Blood Purification (EBP) Device), issued on April 9, 2020;<sup>9</sup> and,

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Decontamination System may be effective at preventing exposure to pathogenic airborne particulates when there are insufficient supplies of FFRs during the COVID-19 pandemic by decontaminating, for a maximum of 20 decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, and that the known and potential benefits of the Battelle Decontamination System, when used to decontaminate compatible N95 respirators for reuse by HCP to prevent exposure to pathogenic airborne particulates during FFR shortages during the COVID-19 pandemic, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the Battelle Decontamination System for decontaminating compatible N95 respirators for reuse by HCP during FFR shortages during the COVID-19 pandemic.

<sup>7</sup> As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the STERIS Sterilization Systems may be effective at preventing exposure to pathogenic airborne particulates when there are insufficient supplies of N95 respirators during the COVID19 pandemic by decontaminating for a maximum of 10 decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, and that the known and potential benefits of the STERIS Sterilization Systems, when used to decontaminate compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic airborne particulates during N95 respirator shortages during the COVID-19 pandemic, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the STERIS Sterilization Systems for decontaminating compatible N95 respirators for reuse by HCP during N95 respirator shortages during the COVID-19 pandemic.

<sup>8</sup> As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized face shields may be effective at preventing HCP exposure to fluid biological airborne particulates during face shield shortages by providing minimal or low barrier HCP protection to the wearer, and that the known and potential benefits of face shields, when used to prevent HCP exposure to such particulates during face shield shortages during COVID-19 outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of these face shields for preventing HCP exposure to such particulates during face shield shortages to prevent disease spread during the COVID-19 pandemic.

<sup>9</sup> As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge may be effective in treating patients 18 years of age or older with confirmed COVID-19 admitted to the intensive care unit (ICU) with confirmed or imminent respiratory failure, and that the known and potential benefits of the Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge, when used to treat COVID-19 patients 18 years of age or older, outweigh the known and potential risks of the Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge; and (3) there is no adequate, approved, and available alternative to the emergency use of the Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge for the treatment of these COVID-19 patients.

- CytoSorbents, Inc.'s, CytoSorb EBP Device, issued on April 10, 2020.<sup>10</sup>

Dated: May 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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<sup>10</sup> As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the CytoSorb device may be effective in treating patients 18 years of age or older with confirmed COVID-19 admitted to the ICU with confirmed or imminent respiratory failure, and that the known and potential benefits of the CytoSorb device, when used to treat such patients, outweigh the known and potential risks of the CytoSorb device; and (3) there is no adequate, approved, and available alternative to the emergency use of the CytoSorb device for the treatment of these COVID-19 patients.

